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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/982,474 | 10/17/2001 | Wilhelmus Theodorus Antonius Maria De Laat | 246152012710 | 8056 |

25225 7590 06/15/2004

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EXAMINER

WINSTON, RANDALL O

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1654

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,474

Applicant(s)

DE LAAT ET AL.

Examiner

Randall Winston

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,15,16,19,20,36,37 and 52-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 15, 16, 19, 20, 36, 37 and 52-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of receipt and entry of the claims filed on January 3, 2004.

Claims 1, 3-8, 15-16, 19-20, 36-37, and 52-63 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 stand rejected under 35 U.S.C.

112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 step a and 52 recite the phrase "the fermentation medium which contains only chemically defined constituents as carbon and nitrogen sources and no complex raw material." The metes and bounds of the above terms cannot be delineated, as applicant fails to set forth the metes and bounds of what the fermentation medium encompasses. It is unclear to examiner of what the fermentation medium encompasses because what the fermentation medium encompasses can be interpret in various ways. (Examiner is clear on the fermentation medium contains carbon and nitrogen sources. However, examiner is unclear on the fermentation medium contains no complex raw materials. Therefore, applicant is suggested to clarify what are those other no complex

raw materials and/or what are no complex raw materials which the fermentation medium contains?)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8, 15-16, 19-20, 36-37, and 52-63 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hogle et al. (Derwent 1987-357537, abstract) in view of Bovenberg et al. (US 5731163) and Microbiology, fourth edition, Peleazar, Reid, and Chan pages 853-856.

Applicant argues there is no motivation to combine the Hogle et al., Bovenberg et al., and Microbiology reference because Hogle et al, Bovenberg et al. al. and Microbiology teach using a fermentation of complex raw material. Moreover, applicant states that the Microbiology reference explicitly teaches an industrial process using a fermentation medium of complex raw material and. Applicant argument, however, is not found persuasive because applicant has not clearly defined what his fermentation medium encompasses (see, 112 2nd. what are those other no complex raw materials

contained within the fermentation medium?). Therefore, examiner's U.S.C. 103 (a) stands because since one of ordinary skill in the art would have been motivated to modify Hogle et al.'s process to include Bovenberg et al.'s process for the beneficial purpose of producing the claimed invention's process of the production of penicillin V and/or adipoyl-7-ADCA because both process utilize the same steps to produce different Beta-Lactams, it would also be an obvious benefit to one of ordinary skill in the art to industrially mass produce Beta-Lactam (i.e. a penicillin) utilizing the claimed invention's standard chemically defined medium because Microbiology, pages 853-856, teaches that penicillin was the first antibiotic to be produced industrially utilizing a similar standard chemically defined medium as the claimed invention's chemically defined medium (see, especially, e.g., page 855-856, the steps).

Moreover, applicant argument is not found persuasive because Microbiology, pages 853-856, teaches it is common to add other chemicals (i.e, carbon and nitrogen sources) to a chemically defined medium for the production the Beta-Lactam (i.e. a penicillin) (see, e.g., page 855, step 5, states the additions of chemicals to the medium serves as precursors for synthesis of penicillin).

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Brumback
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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600